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Certified by

Jon W Dudas

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No.	EV 346 727 328 US

INVENTOR(S)

Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
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☐ *Additional inventors are being named on the _____ separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

DEVICES AND METHODS FOR TRANSPORT OF BODY FLUIDS

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ENCLOSED APPLICATION PARTS *(check all that apply)*

☑ Specification *Number of Pages* 11 ☐ CD(s), Number

☑ Drawing(s) *Number of Sheets* 6 ☑ Other (specify) ~~Application Cover Sheet, and Return~~ Postcard

☐ Application Data Sheet. See 37 CFR 1.76

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

☑ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check or money order is enclosed to cover the filing fees.

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FILING FEE AMOUNT ($): **$80.00**

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☑ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are: _____

Respectfully submitted,

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Date 9/30/03

REGISTRATION NO. *(If appropriate)* 43,209

Docket Number: 38187-2693

Was PTO did not receive the following listed item(s) Small Entity Status

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Attorney Docket No.: 38187-2693

PROVISIONAL PATENT APPLICATION

DEVICE AND METHOD FOR TRANSPORT OF BODY FLUID

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Attorney Docket No.: 38187-2693

DEVICE AND METHOD FOR TRANSPORT OF BODY FLUID

BACKGROUND OF THE INVENTION

The technical field relates to blood sampling and the transport of body fluids to diagnostic instrumentation sensing devices.

Lancing devices are known in the medical health-care products industry for piercing the skin to produce blood for analysis. Typically, a drop of blood for this type of analysis is obtained by making a small incision in the fingertip, creating a small wound, which generates a small blood droplet on the surface of the skin.

Early methods of lancing included piercing or slicing the skin with a needle or razor. Current methods utilize lancing devices that contain a multitude of spring, cam and mass actuators to drive the lancet. These include cantilever springs, diaphragms, coil springs, as well as gravity plumbs used to drive the lancet. The device may be held against the skin and mechanically triggered to ballistically launch the lancet. Unfortunately, the pain associated with each lancing event using known technology discourages patients from testing. In addition to vibratory stimulation of the skin as the driver impacts the end of a launcher stop, known spring based devices have the possibility of firing lancets that harmonically oscillate against the patient tissue, causing multiple strikes due to recoil. This recoil and multiple strikes of the lancet is one major impediment to patient compliance with a structured glucose monitoring regime.

Success rate generally encompasses the probability of producing a blood sample with one lancing action, which is sufficient in volume to perform the desired analytical test. The blood may appear spontaneously at the surface of the skin, or may be "milked" from the wound. Milking generally involves pressing the side of the digit, or in proximity of the wound to express the blood to the surface. In traditional methods, the blood droplet produced by the lancing action must reach the surface of the skin to be viable for testing.

When using existing methods, blood often flows from the cut blood vessels but is then trapped below the surface of the skin, forming a hematoma. In other instances, a wound is created, but no blood flows from the wound. In either case, the lancing process cannot be combined with the sample acquisition and testing step. Spontaneous blood

droplet generation with current mechanical launching system varies between launcher types but on average it is about 50% of lancet strikes, which would be spontaneous. Otherwise milking is required to yield blood. Mechanical launchers are unlikely to provide the means for integrated sample acquisition and testing if one out of every two strikes does not yield a spontaneous blood sample.

Many diabetic patients (insulin dependent) are required to self-test for blood glucose levels five to six times daily. The large number of steps required in traditional methods of glucose testing ranging from lancing, to milking of blood, applying blood to the test strip, and getting the measurements from the test strip discourages many diabetic patients from testing their blood glucose levels as often as recommended. Tight control of plasma glucose through frequent testing is therefore mandatory for disease management. The pain associated with each lancing event further discourages patients from testing. Additionally, the wound channel left on the patient by known systems may also be of a size that discourages those who are active with their hands or who are worried about healing of those wound channels from testing their glucose levels.

Another problem frequently encountered by patients who must use lancing equipment to obtain and analyze blood samples is the amount of manual dexterity and hand-eye coordination required to properly operate the lancing and sample testing equipment due to retinopathies and neuropathies particularly, severe in elderly diabetic patients. For those patients, operating existing lancet and sample testing equipment can be a challenge. Once a blood droplet is created, that droplet must then be guided into a receiving channel of a small test strip or the like. If the sample placement on the strip is unsuccessful, repetition of the entire procedure including re-lancing the skin to obtain a new blood droplet is necessary. The manual dexterity and the relatively large number of devices used to sample and then test the blood challenges patients to keep to their testing regimes.

A still further problem concerns the possible inability to guarantee blood flow from the finger lancet wound to the sensor port located on the disposable cartridge. The problem might be the invariability of the blood volume from the lancet wound, otherwise known as the shape and size of the droplet. There have been stated solutions such as the delivery of the lancet to the finger with a deeper penetration depth or a programmed controlled "lancet-in-the-finger" dwell time to sustain the size of the wound, which

allows more blood to be produced from the wound. However, each might possibly result in a compromise on the degree of pain or sensation felt by the patient.

In some embodiments, a capillary may be co-located with the lancet. In order to get the blood into the capillary, several variables (lateral movement or other variation) come into play. Unless the blood droplet is directly centered on the capillary, there may be difficulty transporting enough blood to the analyte detecting member. For example, if there is any type of lateral movement or if the blood does not fall into the capillary tube, it can smear on the side wall. With an integrated sampling configuration where it may be difficult to visualize where the blood or body fluid is going, there may be no way for the subject to rectify the situation by milking the finger to get a larger droplet and increase the potential of getting the blood in.

SUMMARY OF THE INVENTION

The present invention provides solutions for at least some of the drawbacks discussed above. Specifically, some embodiments of the present invention provide an improved, integrated fluid sampling device. The invention relates to the problems in blood volume invariability during the post lancet wound generation and blood droplet sampling. At least some of these and other objectives described herein will be met by embodiments of the present invention.

In one aspect of the present invention, the invention relates to using an electronic tissue penetration device to drive a penetrating member into tissue, sample the body fluid, and measure analyte levels in the body fluid using a sensor cartridge. The invention uses various techniques to draw body fluid towards an analyte detecting device on the cartridge.

This invention provides a solution to a problem, which concerns the possible inability to guaranteed a stable blood volume from a finger lancet wound to a sensor port located on a disposable cartridge. The problem might be due to shallowness of the lancet penetration depth, skin surface tension issues, or the patient's vascular conditions resulting in the invariability in achieving an adequate blood droplet shape and size. There have been other stated solutions such as the delivery of the lancet to the finger with a deeper penetration depth or a control method to increase the amount of blood to be produced from the wound.

In one embodiment, this invention produces a concept of a capillary need for the blood to travel directly from the wound to the sensor port on the cartridge. Thus the volume of blood produced at the wound site irregardless of its droplet geometry can be completely transported to the analyte detecting member.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The present invention provides a solution for body fluid sampling. Specifically, some embodiments of the present invention provides a method for improving spontaneous blood generation. The invention may use a high density penetrating member design. It may use penetrating members of smaller size, such as but not limited to diameter or length, than those of conventional penetrating members known in the art. The device may be used for multiple lancing events without having to remove a disposable from the device. The invention may provide improved sensing capabilities. At least some of these and other objectives described herein will be met by embodiments of the present invention.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention, as claimed. It may be noted that, as used in the specification and the appended claims, the singular forms "a", "an" and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a material" may include mixtures of materials, reference to "a chamber" may include multiple chambers; and the like. References cited herein are hereby incorporated by reference in their entirety, except to the extent that they conflict with teachings explicitly set forth in this specification.

In this specification and in the claims which follow, reference will be made to a number of terms which shall be defined to have the following meanings:

"Optional" or "optionally" means that the subsequently described circumstance may or may not occur, so that the description includes instances where the circumstance occurs and instances where it does not. For example, if a device optionally contains a feature for analyzing a blood sample, this means that the analysis feature may or may not be present, and, thus, the description includes structures wherein a device possesses the analysis feature and structures wherein the analysis feature is not present.

Referring now to Figure 1, one embodiment of the present invention will now be described. Rather than let a droplet of body fluid build on the surface; one concept is to pull the droplet from the surface with, as a nonlimiting example, a fine mesh 20 that is located between the penetrating member and the finger. Figure 1 shows a top down view of a radial cartridge 21 having the fine mesh 20. At the start position, the lancet mesh 20 may be located between the lancet tip and the foil. When cutting the foil, prior to the lancing event, the cutting instrument will spare the fragile mesh. In this embodiment, the amount of foil can be relatively limited because the mesh will be able to wick the blood down to the analyte detecting member. With the lancet tip being very sharp, the mesh 20 would be pushed to the side rather than cut. The resulting ring of capillary fibers around the wound channel would be available after the lancet was retracted to wick the blood sample into the sample channel.

Figure 2 shows the radial cartridge 21 for use with a lancing device 30. The radial cartridge 21 may be sealed with a sterility barrier 32 and be coupled to analyte detecting members mounted on a substrate 34. A suitable device is described in commonly assigned, copending U.S. Patent Application No. _____ (Attorney Docket No. 38187-2662) fully incorporated herein by reference for all purposes.

Referring now to Figure 3, as described above, when a penetrating member 40 is actuated and extends outward from the cartridge 21, the mesh 20 is pushed aside or pierced by the exiting member 40. The resulting ring of capillary fibers 42 around the wound channel would be available after the lancet was retracted to wick the blood sample into the sample channel.

The physical characteristics of the mesh 20 is one aspect for successfully transport of blood to the analyte detecting member 50. In one embodiment, the mesh 20 could be pliable enough the allow relaxation, but maintain contact or near-contact with the skin surface. An active region could be striped on the mesh to allow the blood to only travel in the direction towards the analyte detecting member. A different gauge capillary fiber may be used on the mains versus the cross. In another embodiment, the mains may have a smaller gage and higher pitch to promote vertical movement. As an additional benefit, if the mesh assisted in distributing the force of lancet impact with the skin, the cutting efficiency of the lancet could be increased.

In another embodiment, the mesh 20 would reduce the amount of micropositioning used to assure that the droplet of body fluid gets to the analyte detecting

member. The potential volume required by the analyte detecting member could be reduced by reducing the amount of blood or body fluid that spontaneously rises to the surface of the skin that is either not removed from the skin once the surface tension is released in a traditional, microfluidics methods. Traditional microfluidics could also have a higher volume required to get the blood to the sample chamber.

Referring now to Figure 4, it should be understood that the mesh may be configured to a variety of geometries. The mesh 20 could be fabricated as a ring as seen in Figure 1 and then heat sealed into the analyte detecting member. The heat sealing should not effect the integrity of analyte detecting member.

As seen in Figure 5, the mesh 20 may be configured so that a blood droplet 60 that hits the mesh 20 will be drawn toward the analyte detecting member 50 as indicated by arrow 62, due to the length of the mesh 20 which is extended down to the member 50. As seen in Figure 4, which is a top down view, the mesh 20 has portions 64 which may be extended down towards the member 50.

In one embodiment, we use a capillary mesh that basically allows the lancet to fire through or the lancet can come around or through a lancet aperture in the mesh. The mesh in one embodiment is a hydrophilic mesh that would then allow the blood to be absorbed, in this embodiment, once the droplet is built up on skin. With mesh, it does not matter where the droplet hits it. With a certain volume, there is enough blood to coat the mesh and coat the analyte detecting member, thus creating a better solution for integrated analyte detecting member.

Figure 6 shows one embodiment where the force of the penetrating member 40 impacting the mesh 20 flattens it out and pushes it against the skin. In this particular embodiment of mesh 20, the mesh 20 is pliable enough to allow relaxation.

One issue associated with the present invention may be getting the analyte detecting member close enough to the lancet. In many embodiments, the radial axis of the lancet is going to be where the droplet of body fluid is going to form. The pickup or transport is going to have to come to the droplet to acquire it.

In one embodiment, a layer of body fluid at least 50-100 microns thick is desired, and this is the thickness that the electrode needs to generate the glucose signal. So if the mesh is sandwiched on top of the electrode or if fluid is wicked along the capillary mesh, it is possible to repeatable transport blood to the analyte detecting member. Electrodes

tend to be hydrophobic. But if there is a hydrophilic mesh, it will still travel to the mesh, even though the surface energy is low.

In another embodiment, a particularly high energy capillary mesh can be co-located at where the droplet is going to come which is at the axis of the lancet travel. The wicking member would be heat sealed to the electrode. Most preferable is a design where the wick is at about 90 degrees (i.e. vertical) as seen in Figure 7.

Referring now to Figure 8, it should be understood that the mesh may be a gradient type of mesh. It may have high energy to pull one way as indicated by arrows 80. The crosses and the mains on the mesh may be designed and patterned to created a desired movement of fluid in contact with the mesh. The resulting effect is a gradient. A thinner gauge may be used in a higher energy area. With regard to the capillary size and the gaps, they are relatively proportionate. Of course, when you get down to a level below 100 microns, 70 microns for the pore size, the mesh can get into blood filtration or clogging of the blood, particulates such as the big lucocytes tend to clog and make the mesh unproductive/effective anyways. There is a limit to how much you can play with sizing of the mesh strands.

It should be understood, of course, that the present invention may operate with alternative embodiments. With the mesh, you may be able to use a hydrophilic spray. Or to create a highly texturized surface or other surface treatment, the mesh may direct the flow of fluid. In some alternative embodiments, a ribbed plastic without pores may be used. One limitation of traditional capillary structure is that when it gets too close to the skin, it tends to blanche or inhibit the movement of blood to the surface. So even if you have it perfectly located in a lateral, collateral direction. Such a capillary structure is vertically sensitive and sometimes does not get the blood as a result.

If the mesh is very compliant, then the vertical sensitivity problem/blanching is substantially resolved. The mesh could be co-located perfectly and touching the surface of the skin. And then you do not have a vertical offset or a vertical insensitivity problem that tends to blanche. Then because there is not a bearing surface there and pressure is kept at a level below that which would cause blanching.

While the invention has been described and illustrated with reference to certain particular embodiments thereof, those skilled in the art will appreciate that various adaptations, changes, modifications, substitutions, deletions, or additions of procedures and protocols may be made without departing from the spirit and scope of the invention.

For example, with any of the above embodiments, the location of the penetrating member drive device may be varied, relative to the penetrating members or the cartridge. With any of the above embodiments, the penetrating member tips may be uncovered during actuation (i.e. penetrating members do not pierce the penetrating member enclosure or protective foil during launch). With any of the above embodiments, the penetrating members may be a bare penetrating member during launch. In some embodiments, analyte detecting members may be printed on the top, bottom, or side of the cavities. The front end of the cartridge maybe in contact with a user during lancing. The same driver may be used for advancing and retraction of the penetrating member. The penetrating member may have a diameters and length suitable for obtaining the blood volumes described herein. The penetrating member driver may also be in substantially the same plane as the cartridge. The sensory material 14 may be deposited into the via holes 18. The conductor material may also be deposited into the via holes. The via holes may be formed by a variety of methods including micro drilling, laser drilling, plasma etching, or the like. The embodiments herein are adapted for use with lancing devices described in U.S. Patent Applications Ser. No. 10/127,395 (Attorney Docket No. 38187-2551US) and U.S. Patent Applications Ser. No. 10/323,622 (Attorney Docket No. 38187-2606US). It should understood that any of the inventions herein may be used in conjunction with devices disclosed in U.S. Patent Applications Attorney Docket No. 38187-2551, 38187-2608, and 38187-2662.

The publications discussed or cited herein are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present invention is not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication provided may be different from the actual publication dates which may need to be independently confirmed. All publications, patents, and patent applications mentioned herein are incorporated herein by reference to disclose and describe the structures and/or methods in connection with which the publications are cited.

Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limit of that range and any other stated or intervening value in that stated range is encompassed within the invention. The upper and lower limits of these smaller ranges may independently be included in the smaller ranges is also

encompassed within the invention, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either both of those included limits are also included in the invention.

Expected variations or differences in the results are contemplated in accordance with the objects and practices of the present invention. It is intended, therefore, that the invention be defined by the scope of the claims which follow and that such claims be interpreted as broadly as is reasonable.

WHAT IS CLAIMED IS:

1. A body fluid sampling device comprising:

a single cartridge;

a plurality of penetrating members coupled to said single cartridge and operatively couplable to the penetrating member driver, said penetrating members movable to extend radially outward from the cartridge to penetrate tissue;

a plurality of analyte detecting member coupled to said single cartridge, said sensors positioned on the cartridge to receive body fluid from a wound in the tissue created by the penetrating member;

a plurality of mesh structures positioned to draw fluid generated by said tissue towards the analyte detecting member.

2. The device of claim 1 further comprising a plurality of electrodes coupled to said analyte detecting member.

3. The device of claim 1 wherein the mesh is a gradient mesh.

ABSTRACT OF THE DISCLOSURE

A body fluid sampling device is provided. This invention produces a concept of a "soccer goal" for the blood to travel directly from the wound to the sensor port on the cartridge. Thus the volume of blood produced at the wound site irregardless of its droplet geometry can be completely transported to the sensor.

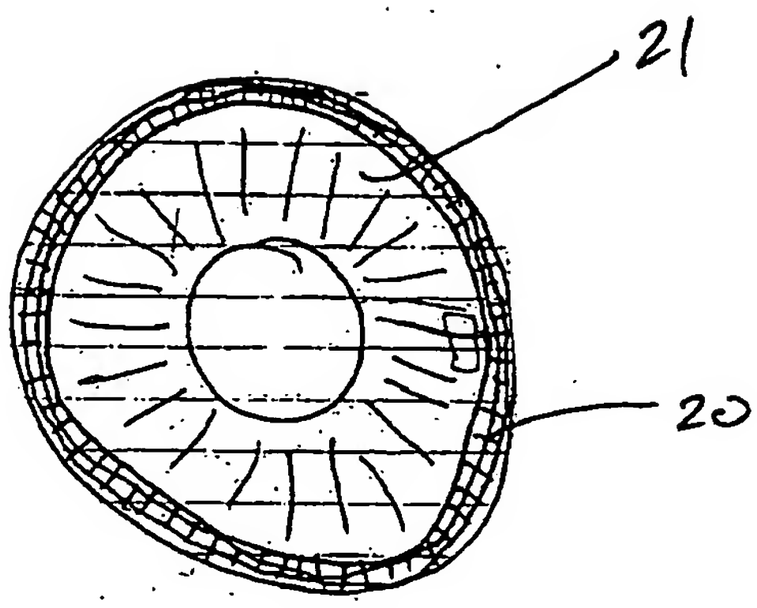

FIG_1

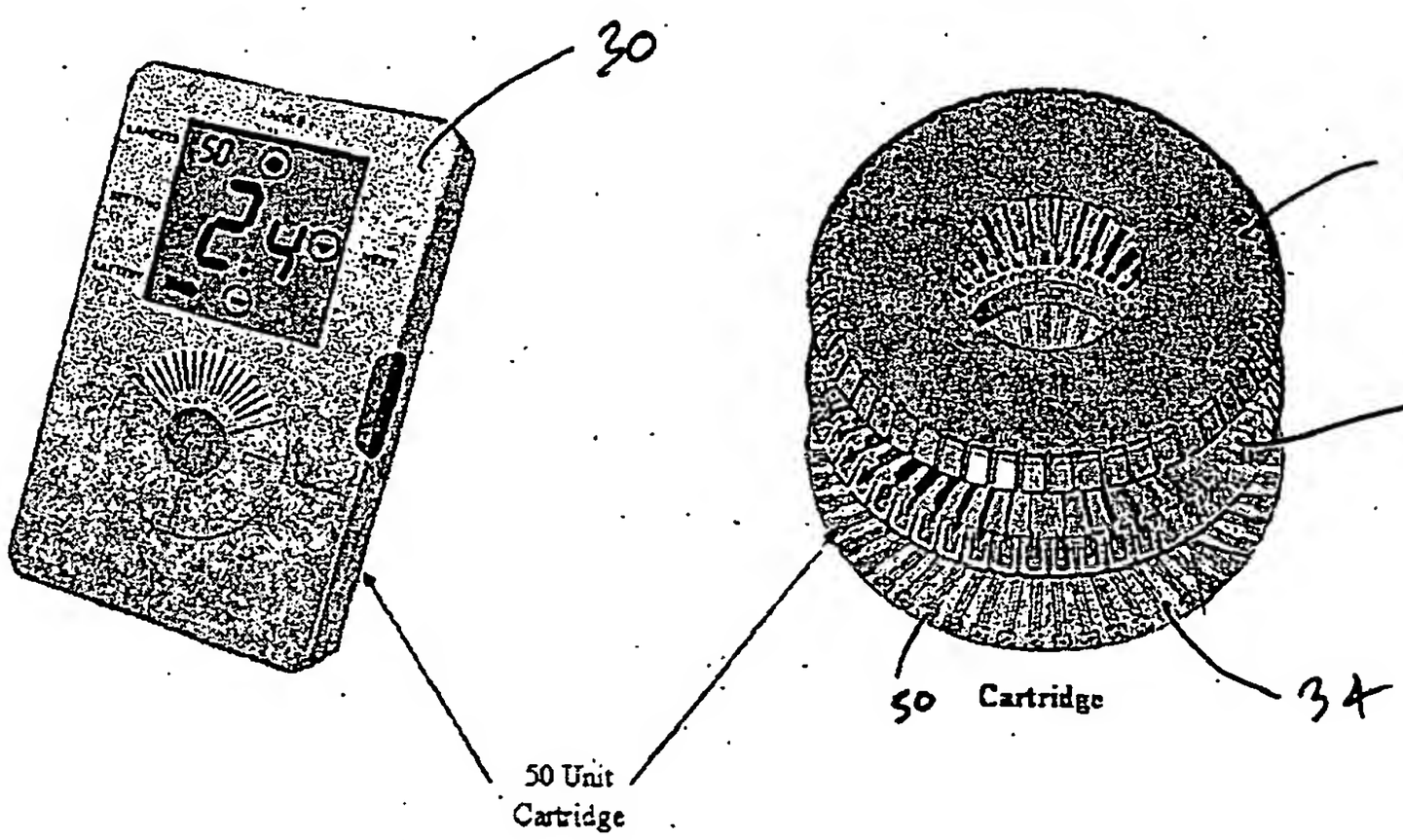

FIG_2

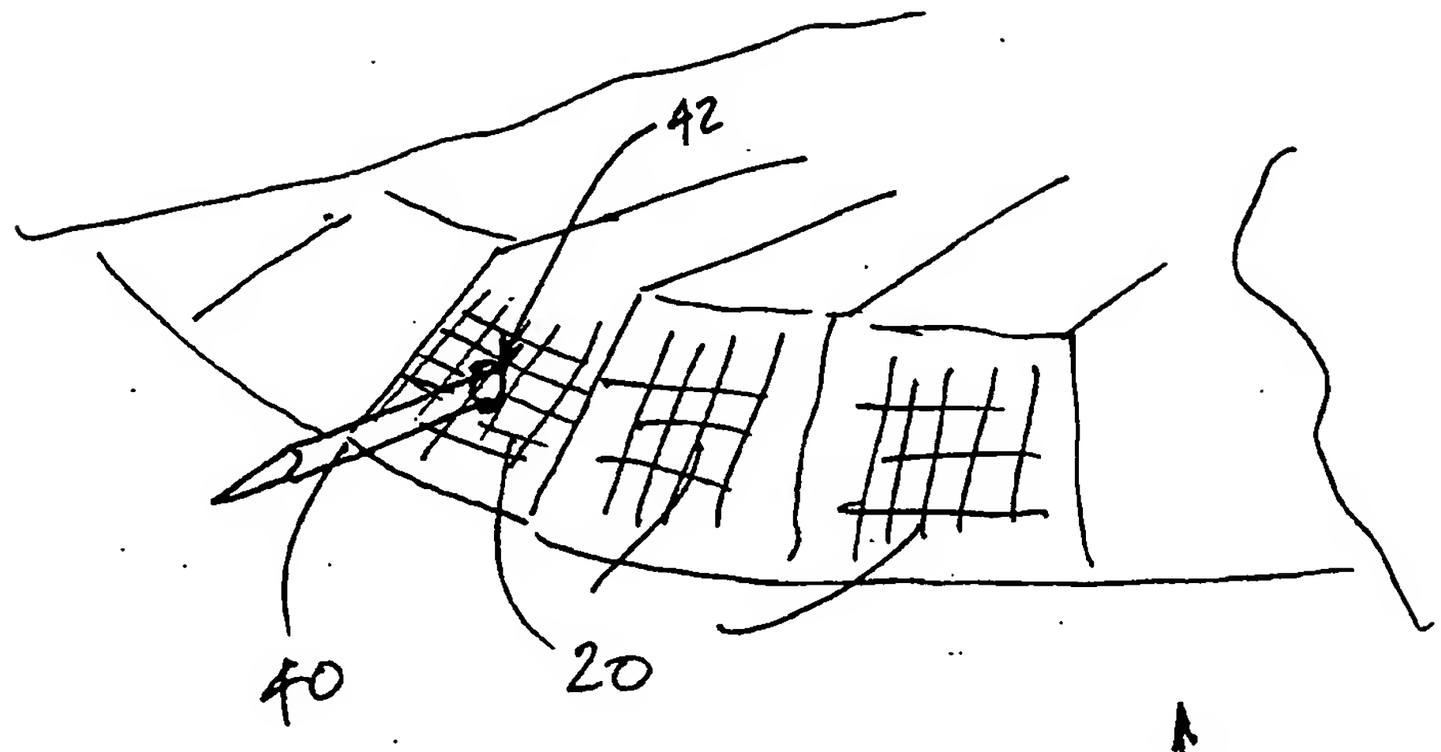

FIG_3

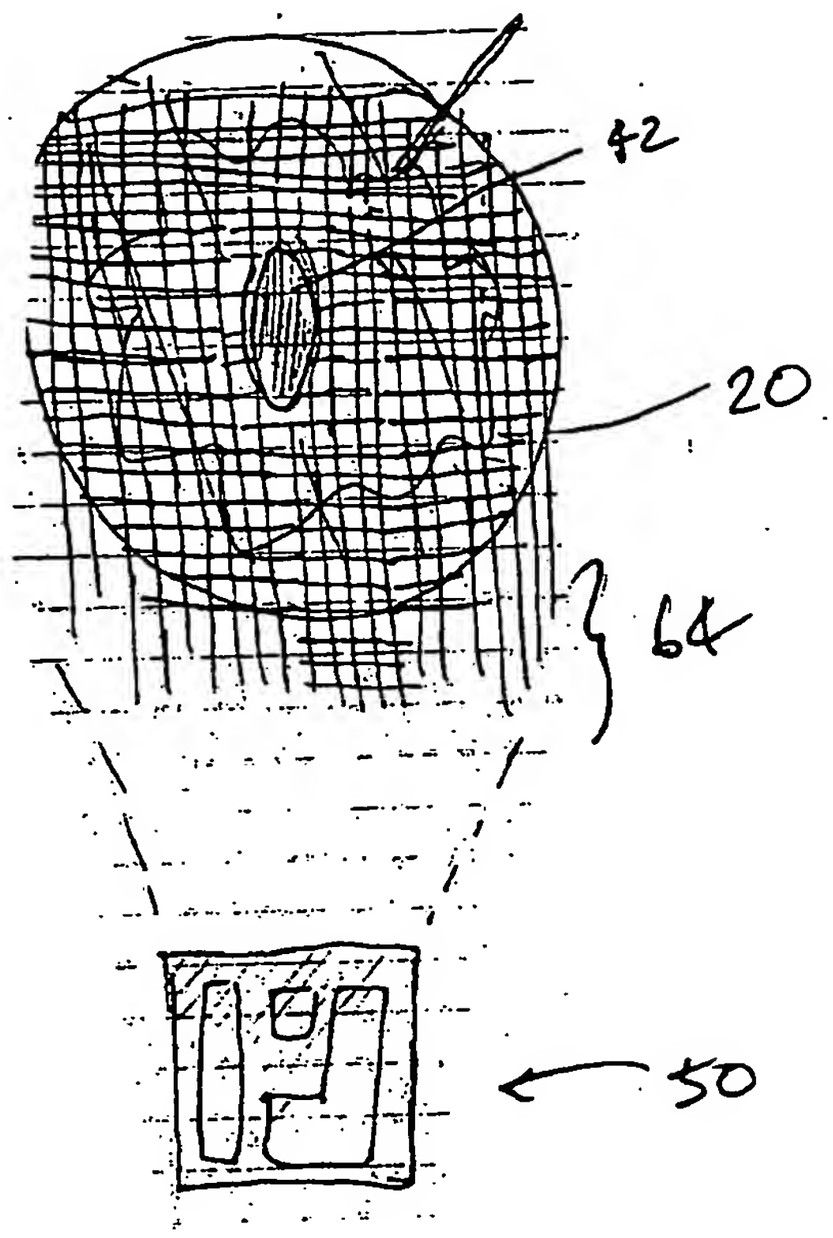

FIG_4

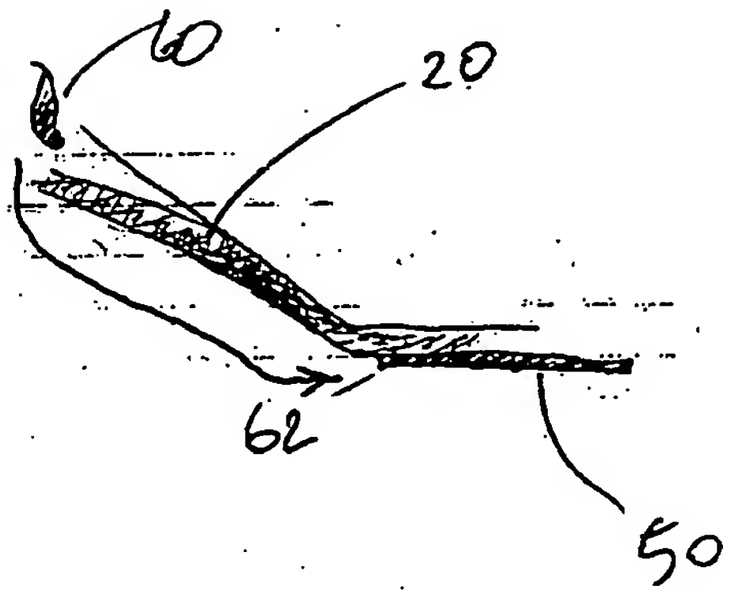

FIG_5

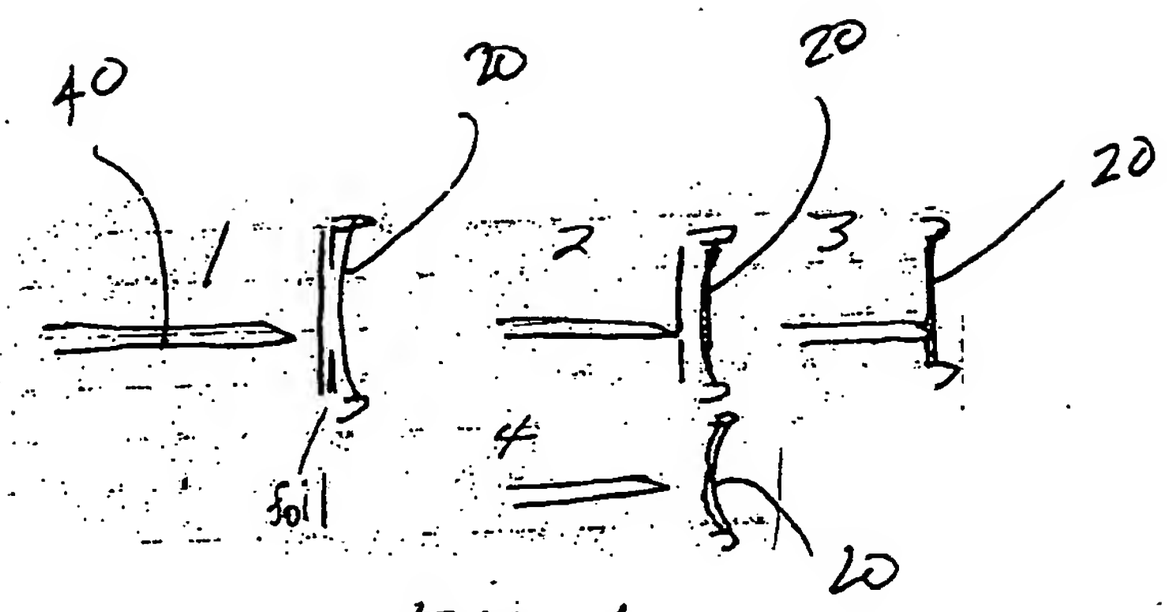

FIG-6

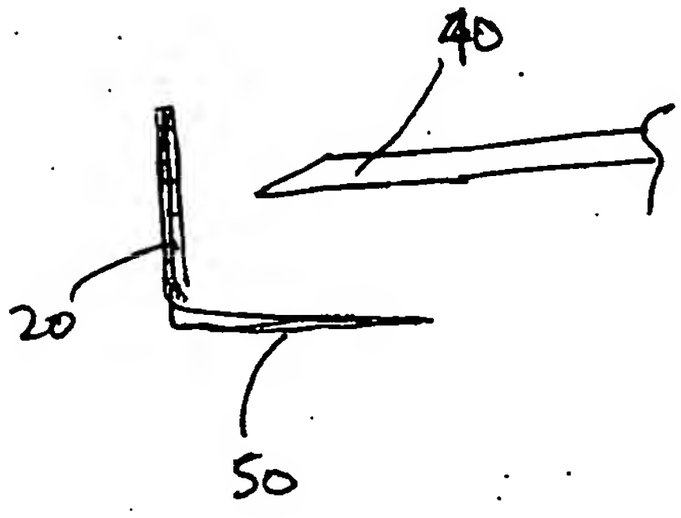

FIG-7

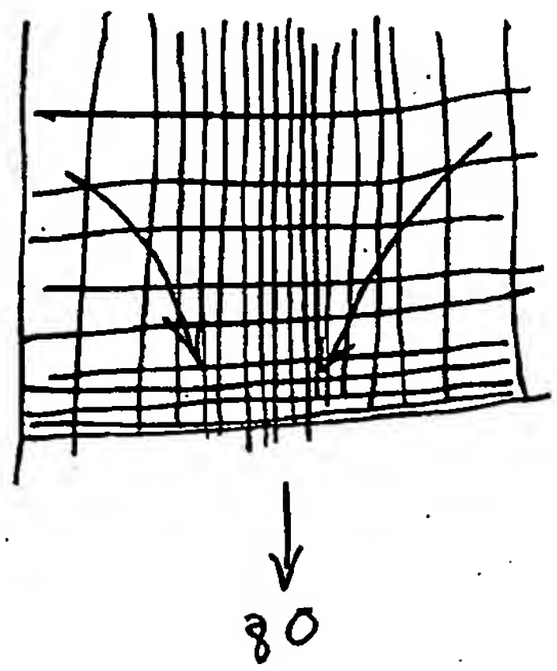

FIG_8

Document made available under the Patent Cooperation Treaty (PCT)

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